

REMARKS

In the Interview Summary of November 20, 2002, the Examiner stated that the Applicant should "... compare the claimed invention with the closest prior art in Krueger and Schulte ..." In the previous Amendment filed June 26, 2003, the Applicants discussed the testing, which is set forth in the Declaration of Dr. Prabhu Gubbi, that the Examiner requested relative to Krueger. The Applicants did not comment on this testing as it applies to Schulte, which is the purpose of this Supplemental paper.

In the Declaration of Dr. Prabhu Gubbi, filed with the Amendment dated June 26, 2003, the Applicants reported the results of tests carried out on titanium implants in which the implants were first blasted with aluminum oxide grit and then exposed to various mineral acids. See Exhibit D. Those tests are relevant to the Schulte reference, which the Examiner contended showed in Figure 14 a surface "identical or substantially identical" to those of the Applicants.

A reference cannot anticipate that which it does not enable. *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 665 (Fed. Cir. 1986); MPEP §2121. It has been long established that a prior reference must contain "such full, clear, and exact terms as to enable any person skilled in the art ... to make, construct, and practice the invention ..." *Seymour v. Osborne*, 78 U.S. 516, 555 (1870). "Mere vague and general representations" will not suffice; the reference must "be an account of a complete and operative invention capable of being put into practical operation." *Id.*

As explained in detail in the Third Information Disclosure Statement dated August 2, 2001, and the Amendment dated April 22, 2002, it is the Applicants' belief that Schulte does not enable one to arrive at the surface illustrated in FIG. 14. Schulte fails to provide any details on

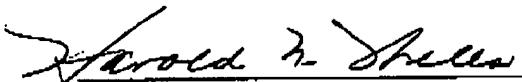
how the grit-blasting and the acid-etching processes were conducted to achieve the disclosed surface. Accordingly, the Applicants' representatives and the Examiner discussed performing a second set of tests on a grit-blasted implant surface that used the same mineral acids that were agreed upon for use in the first set of tests (the first set of tests was focused on acid-etching to overcome Krueger). Of course, a direct comparison with Schulte was not possible because the details of the grit-blasting and the acid-etching processes are not taught by Schulte.

As Dr. Gubbi's results showed, none of the grit-blasted and acid-etched surfaces had the appearance of the Applicants' Osseotite® surface, shown in Exhibit A. Nor do they resemble Fig. 14 of Schulte. In fact, it should be evident from the "before" and "after" etching photographs in Exhibit D that very little effect was obtained when the grit-blasted implants were exposed to the various acids listed in Table D, with one exception. Test 4 showed that a 49 % HF solution appeared to smooth the very rough surface left by grit-blasting. In Test 4, however, there was no fine roughening corresponding to the Osseotite® surface.

It must be concluded that the rough surface produced by grit-blasting was not affected significantly by exposure to nitric, phosphoric, sulfuric and hydrochloric acids at room temperature or elevated temperatures. Furthermore, none of the surfaces resembled the Osseotite® surface, which is the subject of the claimed invention. Therefore, one cannot make the generic statement that a grit-blasted titanium surface that was further acid-etched will produce the claimed implant surface, or even a surface that is similar to the claimed implant surface. If the surface shown in Fig 14 of Schulte is compared with those reported by Dr. Gubbi, it will be evident that Schulte's "mere vague and general representations" of grit-blasting followed by acid-etching is insufficient to enable the skilled artisan to arrive at the surface in

Schulte's FIG. 14. *Seymour v. Osborne*, 78 U.S. at 555. Thus, the Schulte article is not capable of anticipating or rendering obvious the Applicants' claimed implant surface.

Respectfully submitted,



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